

Serial No.: 10/729,035
Docket No.: ECV-5413CIP2CON1
Amendment Dated Monday, April 25, 2005
Responsive to Office Action dated February 8, 2005

REMARKS

Claims 1-30 remain pending in the present application.

The undersigned wishes to express thanks to the Examiner for a courteous and productive telephonic interview on February 28, 2005. The above amendments to claims 13 and 24 were
5 discussed vis-à-vis the cited reference, USPN 5,147,391 to Lane.

Applicants gratefully acknowledge the allowance of claims 1-12.

Claims 13-30 stand rejected under 35 USC §102(b) as being anticipated by Lane. The Examiner references Fig. 11 of Lane which discloses an Elgiloy (metal) frame 12 (i.e., stent) covered with "a seamless tubular cloth or a biological tissue or a flat bias cut cloth 58" (e.g., Dacron). See
10 Col. 7.

Applicants have amended claim 13 to specify that the prosthetic heart valve consists essentially of a flexible stent, a plurality of leaflets, and a suture-permeable connecting band. The flexible stent has an undulating periphery with commissure regions on either side of cusp regions, wherein commissure tips join adjacent commissure regions and the juxtaposed commissure
15 regions define axial spaces therebetween. The connecting band projects outward from the undulating periphery of the stent and provides an interface between the valve and surrounding tissue.

In contrast, the heart valve of Lane includes the Elgiloy (metallic) frame 12 surrounded by the fabric 58, leaflets, and also several other structures that render the valve less than highly
20 flexible. For instance, Fig. 5 illustrates a rigid support ring 14 comprising an annular base 42. Perhaps more significantly, the frame 12 comprises a flat metallic ribbon described at column 6, lines 32-49 as follows:

The commissures of the frame 12 have an extremely low spring constant in the radial direction. The spring constant of my frame alone is approximately 3 gm/mm. As the
25 valve begins to open, therefore, the leaflets can move quite readily in a radial direction, although they would still be constrained circumferentially. As I will explain more fully below, this contributes to an effective stress-strain relationship in the leaflets which approximates that of living tissue.

Best Available Copy

Serial No.: 10/729,035
Docket No.: ECV-5413CIP2CON1
Amendment Dated Monday, April 25, 2005
Responsive to Office Action dated February 8, 2005

5 The flattened shaped of the ribbon 22 gives the frame 20 the desired radial elasticity so that the commissures 24-28 can flex toward the axis of the valve. At the same time, *the frame 20 is relatively stiff circumferentially so that the bending of the commissures will be constrained to a radial direction.* The frame alone can easily be deformed because of its great elasticity. *To maintain the over all annular shape of the valve 10, the relatively rigid annular ring 14 is needed.* (Emphasis added)

10 Therefore, the heart valve of Lane is not highly flexible as provided by a valve constructed in accordance with claim 13. Moreover, the metallic frame 12 covered with the fabric 58, or the fabric 58 alone, is not the same as a suture-permeable connecting band attached to project outward from a stent.

Applicants therefore assert that claims 13 and its dependents are allowable over Lane.

15 Claim 24 has been amended to specify that the connecting band includes a suture-permeable inner member surrounded by a fabric cover. Again, the Examiner had reference to Fig. 11 of Lane in rejecting this claim. As discussed in the interview, the metallic frame 12 is not highly flexible and is not suture-permeable. Moreover, Fig. 11 of Lane does not disclose a connecting band for a heart valve, but instead discloses an inner structural frame covered with fabric. The fabric is used to attach the structural frame to the remaining parts of the valve, and is not a connecting band, as defined in the present application (i.e., an interface between the
20 prosthetic valve and the surrounding tissue). The function of the connecting band is analogous to a sewing ring, although that term is not used because the band is not a ring and because the connecting band may sewn to the surrounding tissue or attached with structure other than sutures (such as, e.g., staples, clips, or adhesive).

25 Accordingly, Applicants believe that claim 24 and its dependents are allowable over Lane.

Serial No.: 10/729,035
Docket No.: ECV-5413CIP2CON1
Amendment Dated Monday, April 25, 2005
Responsive to Office Action dated February 8, 2005

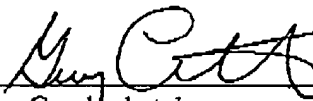
In view of the above amendments and remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (773) 857-7634.

5

Respectfully submitted,

Date: April 25, 2005

10


Guy Cumberbatch
Registration No. 36,114
Telephone: (773) 857-7634
c/o Debra Condino
Registration No. 31,007
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6803
Facsimile: (949) 250-6850
Customer No. 30452

15

20

Best Available Copy